ATTORNEY DOCKET NO: **D0188.70126US00**

T.H. 1-2-03 #15/Decl.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Darois, et al.
Serial No:	09/900,707
Filed:	July 6, 2001
For:	PROSTHETIC REPAIR FABRIC
Examiner:	David A. Bonderer
Art Unit:	3732
Confirmation No:	4890

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF STEPHEN N. ELDRIDGE UNDER 37 CFR § 1.132

I, Stephen N. Eldridge, declare as follows:

1. I received a Masters of Science degree in Animal Pathology from the University of Rhode Island (1982). I hold a Bachelor of Science degree in Biology from Edinboro State University, Edinboro Pennsylvania (1979).

2. Since 1986, I have been employed by several divisions of C.R. Bard, Inc., which is the assignee of the above-identified patent application. From 1986 to 1995, I worked for Bard Vascular Systems (formerly known as Bard Cardio-Surgery) conducting research and development of vascular grafts, including protein coating of vascular grafts. In the early 1990's, I became involved in the research and development of soft tissue repair prosthetics, including mesh repair fabrics. In 1995, I transferred to Davol, Inc., another division of C.R. Bard, where I have continued my work on the research and development of soft tissue repair prosthetics. From 1995 to 1997, I was a senior development engineer at Davol responsible for the development and commercialization of soft tissue repair products. Since 1997, I have been the Manager of Research & Development for Hemostasis and Soft Tissue Repair Products at Davol. I am responsible for supervising a team of development engineers involved with the R&D and commercialization of soft tissue repair prosthetics.

3. Since 1992, my primary work has focused on the interaction of biomaterials with tissue, and more specifically on the ingrowth of tissue to biomaterials and the prevention of tissue ingrowth and subsequent adhesions to biomaterials.

4. To date, I am an inventor on seven (7) U.S. patents issued to C.R. Bard, and an inventor on several pending U.S. patent applications, including the present application.

5. I am familiar with the level of knowledge possessed by those of ordinary skill in the art of soft tissue repair prosthetics as of the filing date of the present application. My comments below are based upon my appreciation of industry knowledge as of that timeframe.

6. I understand that the Examiner in charge of handling the above-identified application has rejected the claims as being unpatentable over Mulhauser (U.S. patent No. 5,766,246). I have reviewed this reference, the pending independent claims, the Final Office Action of July 25, 2003, and the Examiner Interview Summaries mailed on September 29, 2003 and October 23, 2003. I respectfully disagree with the Examiner's position relative to the reference, as detailed below.

7. Mulhauser is directed to an implantable prosthesis 10 having a mesh layer 12 and a semi-rigid frame 14 supporting the mesh layer. (Mulhauser, Col. 3, lines 39-49). As shown in Fig. 3(h), the frame may be configured to extend over the mesh layer at both the peripheral edge of the mesh layer and the surface margin of the mesh layer adjacent the peripheral edge.

8. I understand the Examiner has taken the position that the Mulhauser frame 14 is a barrier to adhesions with tissue and muscle, forming both an edge barrier and a surface barrier. More particularly, I understand the Examiner to maintain that the frame 14 is an adhesion resistant barrier on the basis that it may be made of silicone material. I do not find anything in Mulhauser to suggest the frame as being adhesion resistant. Mulhauser does not teach or suggest that the frame 14 has any type of adhesion inhibiting properties. Mulhauser only indicates that the frame 14 may be formed from an injection molded polypropylene or silicone material, or that

the frame may be formed by hot or cold forming a ring-shaped depression in the mesh layer itself. (Mulhauser, Col. 4, lines 60-65).

9. The adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors such as the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately 10μm or more is susceptible to adhesions with tissue or muscle.

10. Mulhauser provides no teaching or suggestion as to any structural characteristics of a silicone frame that would determine its adhesion resistant properties. As indicated above, Mulhauser discloses only that the frame may be formed from an injection molded silicone material. However, the surface texture and porosity of a silicone frame (as well as a molded polypropylene frame) can vary depending on the specific design parameters of the mold used to form the frame. Therefore, a molded silicone frame can promote tissue ingrowth and adhesions with tissue and muscle. Thus, the fact that the Mulhauser frame may be injection molded from a silicone material does not lead me to the conclusion that the frame inhibits adhesions to tissue and muscle. I also believe that one of ordinary skill in the art would not consider the Mulhauser frame, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle.

11. I understand the Examiner also contends that Fig. 3(h) of Mulhauser supports his position that the frame inhibits tissue ingrowth on the basis that the figure shows a smooth silicone layer. I respectfully disagree. Nothing in the figure provides any indication that the frame is adhesion resistant. As indicated above, the adhesion resistance of a material implanted in a body depends on the surface texture and porosity of the material and that tissue ingrowth can occur when the surface texture or porosity is approximately 10μm or more. This amount of surface texture and porosity is microscopic and undetectable with the naked eye. Thus, simply because the drawing in Mulhauser does not illustrate a rough surface or large pores does not

indicate to me that the frame is resistant to tissue ingrowth or adhesions. I also believe that one of ordinary skill in the art would not consider the frame to be adhesion resistant based on the drawings.

12. I understand the Examiner further contends that the Eldridge patent (U.S. Patent No. 6,120,539) supports his position that silicone material inhibits tissue ingrowth. In particular, the Examiner alleges that the Eldridge patent discloses that silicone elastomer discourages ingrowth and serves as a suitable barrier layer. (Citing col. 3, line 60 to col. 4, line 5). I am one of the co-inventors on the Eldridge patent and, therefore, very familiar with its teachings. I have also reviewed the reference and respectfully disagree with the Examiner's position. Eldridge discloses a prosthetic repair fabric that includes a dual layer fabric 12, 14 that is covered with a barrier material 16 that does not substantially stimulate adhesion formation when implanted in tissue. A silicone elastomer is one of several disclosed materials that may be used as a suitable barrier material. However, this teaching in Eldridge does not support the Examiner's position that the Mulhauser frame is adhesion resistant. As indicated above, the adhesion resistant properties of a prosthetic material is affected by the structural properties, including surface texture and porosity, of the formed material. An adhesion resistant barrier layer, such as employed on the Eldridge repair fabric, requires a microporous structure having a surface texture or porosity that is less than 10μm. This is not an inherent property of the material itself, but varies depending upon the structure formed with the material, whether it is a silicone elastomer or other material. Thus, the fact that a silicone elastomer may be employed as a barrier material does not support a conclusion that any structure formed from a silicone elastomer, such as the Mulhauser frame, is necessarily adhesion resistant. I also believe that one of ordinary skill in the art would recognize that an adhesion resistant barrier requires a microporous structure and that structures formed from a silicone elastomer are not necessarily microporous and adhesion resistant.

13. For the foregoing reasons, I find no support for the Examiner's position that the Mulhauser frame 14, even if formed from a silicone elastomer, inhibits the formation of adhesions with tissue or muscle. More particularly, Mulhauser fails to teach or suggest any structural characteristics that affect the adhesion resistant properties of the frame 14. I also

believe that one of ordinary skill in the art would not consider the Mulhauser frame 14, even if formed of a silicone elastomer, as necessarily inhibiting the formation of adhesions with tissue or muscle.

I, the undersigned, declare that all statements herein of my own knowledge are true and that all statements made on information and belief are believed to be true. And further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of title 18 of the United States code and that such willful false statements may jeopardize the validity of this document and any patent which may issue from the above-identified patent application.

12/22/03
Date

Stephen N. Eldridge
Stephen N. Eldridge